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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/519,821	09/28/2005	Henry Daniell	CHL-T107C2Z2	3102

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EXAMINER	
KUBELIK, ANNE R	

ART UNIT	PAPER NUMBER
1638	

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07/11/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/519,821	DANIELL, HENRY	
	Examiner	Art Unit	
	Anne R. Kubelik	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-25 and 27-39* is/are rejected.

7)☐ Claim(s) *26* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *30 December 2004* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-39 are pending.

2. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

3. Fig 2-3 and 30-31, are objected to because no details can be made out. Fig 8-23, 25-29 and 38 are objected to because the lettering the black boxes cannot be made out.

Sequence Rules

4. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825.

Sequence identifiers are missing from the sequences in pg 52, lines18.

Full compliance with the sequence rules is required in response to this Office action. A complete response to this Office action must include both compliance with the sequence rules and a response to the issues set forth herein. Failure to fully comply with both of these requirements in the time period set forth in this Office action will be held to be non-responsive.

Claim Objections

5. Claim 26 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only. See MPEP § 608.01(n). Accordingly, the claim has not been further treated on the merits.

6. Claims 32-33 and 38 are objected to because of the following informalities:

In claim 32, line 1 "no-green" should be replaced with --non-green--.

In claim 33, line 3 "plastd" should be replaced with --plastid--.

In claim 38, line 4 "betain aldhyde" should be replaced with --betaine aldehyde--.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 23-24, 32 and 38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention. Dependent claims are included in all rejections.

Claims 23 and 24 are indefinite because it is not clear if the progeny and seed comprise the vector; unless the parent plant is the female parent, the progeny and seed will not comprise the vector.

Claim 32 is indefinite because it recites no method steps.

Claim 38 is indefinite because it fails to recite the claim number in line 3.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1-4, 7, 13-14, 16-17, 20-25, 27-37 and 39 are rejected under 35 U.S.C. 102(b) as being anticipated by Daniell (WO 99/10513) taken with the evidence of the instant specification.

Daniell discloses a plastid transformation vector comprising a first flanking sequence (rbcL or 16S/trnI), a promoter (Prrn or PatpB), a selectable marker (aadA), a heterologous DNA coding for a foreign gene (EPSPS, EG121, mGFP4, hph, CryIIA), a 3' UTR (psbA 3'), and a second flanking sequence (ORF512 or trnA) (Fig. 2-3, 5-8). Both sets of flanking sequences are conserved in the plastid genome of higher plant species (pg 20, lines 20-34) and are transcriptionally active spacer regions (pg 9, lines 6-22). The instant specification teaches that the Prn promoter is functional in green and a non-green plastids (pg 39, lines 4-7), and that the psbA 3' UTR provides transcript stability to the DNA coding for a foreign gene (pg 44, line 32, to pg 45, line 1).

Daniell also discloses Arabidopsis plants whose plastids are transformed via their roots with the vectors (pg 50, lines 17-21). Daniell also discloses somatic embryos transformed with the vectors (pg 50, line 17, to pg 51, line 4). Further, all the plants whose plastids are transformed with these vectors in Daniell (pg 42-51) would have roots and other non-green plant parts whose plastids comprise the vector; these non-green plant parts would be capable of regenerating through somatic embryogenesis. Green or non-green plant cells transformed with the vector that are regenerated via somatic embryogenesis would be structurally identical to green or non-green plant cells, respectively, transformed with the vector that are not regenerated via somatic embryogenesis. Daniell et al discloses progeny and seeds of plants transformed with

one of the vectors (pg 59, line 32, to pg 60, line 9). Growing the plant cells would express the protein of interest.

11. Claims 1-4, 7, 13-14, 16-25, 28-31, 33-39 are rejected under 35 U.S.C. 102(b) as being anticipated by Daniell et al (2001, Curr. Genet. 39:109-116) taken with the evidence of the instant specification.

Daniell et al disclose a plastid transformation vector comprising a first flanking sequence (16S/trnI), a promoter (Prrn), a heterologous DNA coding for a foreign gene (aadA), a selectable marker (BADH), a 3' UTR (psbA 3'), and a second flanking sequence (trnA) (Fig. 1). Alternately, aadA could be the selectable marker and BADH the gene of interest. Both flanking sequences are conserved in the plastid genome of higher plant species and are transcriptionally active spacer regions (paragraph spanning the columns on pg 111). The instant specification teaches that the Prn promoter is functional in green and a non-green plastids (pg 39, lines 4-7), and that the psbA 3' UTR provides transcript stability to the DNA coding for a foreign gene (pg 44, line 32, to pg 45, line 1).

Daniell et al also disclose tobacco plants whose plastids are transformed with the vector and progeny and seeds from the transformed plants (pg 112, left column, paragraph 3, to right column, paragraph 3; pg 115, left column, paragraph 2). The plants transformed with this vector would have roots and other non-green plant parts whose plastids comprise the vector; these non-green plant parts would be capable of regenerating through somatic embryogenesis. Green or non-green plant cells transformed with the vector that are regenerated via somatic embryogenesis would be structurally identical to green or non-green plant cells, respectively, transformed with the vector that are not regenerated via somatic embryogenesis. Growing the plant cells would express the protein of interest, including BADH.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13. Claims 1-4, 7, 10-14, 16-17, 20-25, 27-37 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Daniell (WO 99/10513).

The claims are drawn to plastid transformation vectors in which one flanking sequence is a 4 kb long region comprising 16S/trnI and the other is a 4 kb long region comprising trnA/23S.

The teachings of Daniell are discussed above. Daniell does not disclose flanking sequences that are 4 kb long or comprise trnA/23S.

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to modify the plastid transformation vectors taught by Daniell to make the flanking sequences 4 kb long. One of ordinary skill in the art would have been motivated to do so because Daneill suggests using longer flanking sequences and including all or part of 16S and 23S (pg 20, lines 29-34; pg 22, lines 4-11). Flanking sequences that are about 4 kb long would be made in the optimization of vectors.

14. Claims 5-6 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Daniell (WO 99/10513) as applied to claims 1-4, 7, 10-14, 16-17, 20-25, 27-37 and 39 above, and further in view of Maliga et al (1999, US patent 5,877,402).

The claims are drawn to plastid transformation vectors with psbA 5'UTRs.

The teachings of Daniell are discussed above. Daniell does not disclose psbA 5' UTRs in the vectors.

Maliga et al teach a variety of plastid transformation vectors with 5' and 3'UTRs, including 5' and 3' UTRS from psbA (Fig 22B and C).

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to modify the plastid transformation vectors taught by Daniell to include the vector the psbA 5' UTR described in Maliga et al. One of ordinary skill in the art would have been motivated to do so because Maliga et al teaches that 5'UTRs, especially that of psbA, improve expression of the protein of inertest (column 24, line 63, to column 25, line 49).

15. Claims 6 and 8-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Daniell (WO 99/10513) as applied to claims 1-4, 7, 10-14, 16-17, 20-25, 27-37 and 39 above, and further in view of McBride et al (1999, US patent 5,925,806).

The claims are drawn to plastid transformation vectors with the T7 gene 10 5'UTR and the rps16 3'UTR.

The teachings of Daniell are discussed above. Daniell does not disclose the T7 gene 10 5'UTR and the rps16 3'UTR in the vectors.

McBride et al teach plastid transformation vectors with the T7 gene 10 promoter and 5'UTR (column 15, line 27-47) and the use of the rps16 3'UTR (Fig 2).

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to modify the plastid transformation vectors taught by Daniell to include the T7 gene 10 promoter and 5'UTR and the rps16 3'UTR described in McBride et al. One of ordinary skill in the art would have been motivated to do so because the T7 gene 10 promoter and 5'UTR allow regulation of expression from tissue-specific or inducible promoters in the nucleus (McBride et

al, column 2, lines 42-54); additionally, the T7 gene 10 5'UTR has a strong ribosome binding site, which would improve translation of the protein of interest (column 15, line 27-47). Choice of 3'UTR, including the rps16 3'UTR, is an effective parameter that a person of ordinary skill in the art would routine optimize. Optimization of parameters is a routine practice that would be obvious for one of ordinary skill in the art to employ to best achieve the desired results.

Conclusion

16. No claim is allowed.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, whose telephone number is (571) 272-0801. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg, can be reached at (571) 272-0975.

The central fax number for official correspondence is (571) 273-8300.

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Anne Kubelik, Ph.D.
July 2, 2007

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PRIMARY EXAMINER